

IN THE CLAIMS:

Please amend the claims pursuant to 37 C.F.R. 1.121 as follows (see the accompanying "marked up" version pursuant to 1.121):

Please cancel claims 1-46 and 94 without prejudice.

Please amend the following claims.

*Sub
PDI*
47. (Amended) A sustained release therapeutic nail varnish composition comprising:

- C1*
- (a) an antifungal effective amount of an antifungal agent;
 - (b) a keratolytic agent in an amount sufficient to increase permeability of the nail;
 - (c) greater than 3% (w/w) of a humectant to trap water;
 - (d) water in an amount sufficient to hydrate the nail and thereby to increase permeability of the nail in combination with said keratolytic agent;
 - (e) a polymeric film forming agent selected to form a sustained release film upon application of said composition on a nail and evaporation of said volatile solvent; and
 - (f) a volatile solvent;

said sustained release film configured to trap water from said composition and maintain it in contact with said nail, said water and said humectant in combination

C1
conclude
facilitating penetration of said antifungal agent into the nail, and thereby enhancing therapeutic effectiveness of said antifungal agent.

C2
51. (Amended) The nail varnish of claim 47, wherein said antifungal agent is present in an amount of less than about 5% of the total weight of the composition excluding said volatile solvent.

C3
55. (Amended) The nail varnish of claim 47, wherein said keratolytic agent is present in an amount of from about 0.05% to about 5% of the total weight of the composition excluding said volatile solvent.

C4
59. (Amended) The nail varnish of claim 56, wherein said antibacterial agent is present in an amount of from about 0.05% to about 5% of the total weight of the composition excluding said volatile solvent.

C5
62. (Amended) The nail varnish of claim 56, wherein said antiviral agent is present in an amount of from about 0.8% to about 8% of the total weight of the composition excluding said volatile solvent.

C6
65. (Amended) The nail varnish of claim 56, wherein said antipsoriatic

C6
conceded agent is present in an amount of from about 0.1% to about 10% of the total weight of the composition excluding said volatile solvent.

C7
68. (Amended) The nail varnish of claim 47, wherein said humectant is present in an amount of from about 5% to about 35% of the total weight of the composition excluding said volatile solvent.

C8
70. (Amended) The nail varnish of claim 47, wherein said water is present in an amount of from about 0.4% to about 25% of the total weight of the composition excluding said volatile solvent.

C9
76. (Amended) The nail varnish of claim 47, wherein said polymeric film forming agent is present in an amount of from about 8% to about 35% total weight of the composition excluding said volatile solvent.

C10
82. (Amended) The nail varnish of claim 47, further comprising a plasticizer.

C11
85. (Amended) The nail varnish of claim 82, wherein said plasticizer is present in an amount of from about 0.5% to about 10% of the total weight of the

C11
conceded
composition excluding said volatile solvent.

C12
93. (Amended) A method of preparing a sustained release therapeutic varnish formulation, comprising the steps of:

- (a) preparing a solution comprising water and a volatile solvent;
- (b) adding water to the solution prepared in (a);
- (c) dissolving a keratolytic agent and an antifungal agent into the solution prepared in (b);
- (d) adding an humectant to the solution prepared in (c); and
- (e) dissolving a polymeric film forming agent in the solution prepared in (d);

said film forming agent being selected so as to form a sustained release film upon application of the formulation on a nail and evaporation of said volatile solvent, said sustained release film configured to trap water in contact with the nail and the surrounding tissues.

C13
96. (Amended) A sustained release therapeutic nail varnish composition comprising:

- (a) an antifungal effective amount of an antifungal agent;
- (b) a keratolytic agent in an amount sufficient to increase

permeability of the nail;

(c) a humectant to trap water;

(d) a polymeric film forming agent;

(e) water; and

(f) a volatile solvent; wherein upon application on a nail, the volatile solvent evaporates and a sustained release film coating forms on the surface of the nail, the sustained release film coating releasing the antifungal and keratolytic agents in respective effective amounts over a prolonged period of time and trapping water in contact with the nail; the humectant retaining water in the film; and said keratolytic agent and said water increasing permeability of the nail surface and facilitating penetration of the released antifungal agent below the nail surface.

Please add the following new claims:

98. (New) A method of treating a fungal infection comprising administering to a subject a therapeutically effective amount of a sustained release therapeutic nail varnish composition, wherein the composition comprises:

(a) an antifungal amount of an antifungal agent;

(b) a keratolytic agent in an amount sufficient to increase permeability of the nail;